

ART 34 AMDT

International Application No: PCT/CA03/01175

International Patent Classification No: A61K9/16

Applicant:

Bernard Charles Sherman

Title:

**DUAL-SPIKE RELEASE FORMULATION
FOR ORAL DRUG DELIVERY**

Filing Date:

August 6, 2003

AMENDED CLAIMS – November 18, 2004

1. A composition for oral administration which achieves drug release in two spikes, said composition comprising particles of a homogenous mixture of methylphenidate or a salt thereof and an enteric polymer, wherein the ratio of enteric polymer to methylphenidate or a salt thereof is greater than 4 and less than 100.
2. The composition of any of claims 1 wherein the enteric polymer is polyvinyl acetate phthalate.
3. The composition of any of claims 1, or 2, wherein the ratio of enteric polymer to drug is greater than 4 to about 50.
4. The composition of any claim 1, or 2 wherein the ratio of enteric polymer to drug is from about 10 to about 20.
5. The composition of any previous claim wherein said particles of the composition further comprise granules sized so as to pass through a #8 mesh screen but not pass through a #16 mesh screen.
6. The composition any previous claim wherein some of the drug is released promptly, after ingestion, when the composition reaches the stomach and release of the balance is delayed until the particles reach the small intestinal.

Empf.zeit: 18/11/2004 21:20

Empf.nr.: 035 P.005

AMENDED SHEET